DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 23, 2015

Orthomerica Products, Inc.
Mr. David L. Hooper
Manufacturing Engineer
6333 North Orange Blossom Trail
Orlando, Florida 32810

Re: K142141
Trade/Device Name: STARband®, STARlight®
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA, OAN
Dated: March 18, 2015
Received: March 20, 2015

Dear Mr. Hooper,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142141

Device Name
STARband and STARlight

Indications for Use *(Describe)*
The STARband and STARlight are intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. These devices are also indicated for adjunctive use for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have moderate-to-severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. Applicant Information

Name: Orthomerica Products, Inc.
Address: 6333 North Orange Blossom Trail
Orlando, FL 32810
Telephone: (407) 290-6592
Facsimile: (407) 290-2419

FDA Establishment Registration Number

1058152

Contact Information

Contact Person: David Hooper, Manufacturing Engineer
Address: 6333 North Orange Blossom Trail
Orlando, FL 32810
Telephone: (407) 290-6592
Facsimile: (407) 290-2419
Email: dhooper@orthomerica.com
Date Prepared: August 1, 2014

II. Submission Information

Type: Traditional 510(k) Submission
Proprietary Name: STARband® and STARlight®
Common Name: Cranial Orthosis
Classification: Class II (special controls); OAN; MVA; 21 CFR 882.5970
Classification Name: Cranial Orthosis

III. Manufacturer Site

Name: Orthomerica Products, Inc.
Address: 6333 North Orange Blossom Trail
Orlando, FL 32810
Telephone: (407) 290-6592
Facsimile: (407) 290-2419
FDA Establishment Registration Number: 1058152

IV. Description of Device/Modification

The STARband and STARlight redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or 3-dimensional captured image of the infant's head to acquire the existing shape. The mold is sealed and filled with plaster or the 3-dimensional image is carved from a rigid polyurethane foam blank to create a positive model of the head shape. The positive model is modified to obtain greater symmetry and space in the areas of flattening. The STARband and STARlight provide total contact over the prominent or bossed areas of the baby's head to discourage growth there. Over the course of treatment, the inside of the band is further modified by the practitioner to provide space for growth to occur in the flat or depressed areas. The shape of the STARband and STARlight directs growth into the areas of least resistance and creates a precise pathway for the head shape to improve in symmetry and proportion.

The STARband and STARlight product families as it was released in K140353 are essentially still the same devices. The STARband Side Opening design and STARband Bi-Valve design is made with an outer shell of 5/32" polyethylene-polypropylene copolymer plastic with an inner liner made of 1/2" pelite polyethylene foam or 1/2" Aliplast foam (closed cell polyethylene). The STARlight Side Opening design and the STARlight Bi-Valve design are made of a plastic shell of 5/32" – 1/4" clear Surlyn or 1/8" - 7/32" Clear Co-Polyester. The STARlight PRO (Post-operative Remolding Orthosis) design is made of 1/4" to 3/8" clear Surlyn. Optional Aliplast (closed cell polyethylene) padding is available for the clear plastic bands and in addition, optional Reston (polyurethane – 3M Medical Product) foam is available for the STARlight PRO design.

The STARband Side Opening design and the STARlight Side Opening design has a top opening and a side opening. The band is held in place by a Velcro® strap (1½" for STARband Side Opening and 1" for STARlight Side Opening) across the side opening. The STARlight PRO has two side openings, no top opening, and is held in place by a Velcro strap across each side opening. The STARlight Bi-Valve design and the STARband Bi-Valve design consist of two plastic shells that overlap with a superior sliding mechanism. The right and left overlap tabs are connected via a Velcro strap with chafe and loop.

The proposed device modification is a new software component for a previously cleared shape capture method, the STARscanner™ Data Acquisition System. The new software component is the Cranial Comparison Utility (CCU). The CCU is a separate software program that is designed to present specific measurements derived from a three-dimensional (3D) digital model of a patient's cranium. These features are useful to

medical professionals by providing more detailed shape data that can be incorporated into the patient evaluation/assessment and for tracking cranial head shape changes.

V. Statement of Indications and Intended Use

Statement of Indications:

The STARband and STARlight are intended for medical purposes for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The devices are also indicated for adjunctive use for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have moderate-to-severe cranial deformities including plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads.

Intended Use:

The STARband and STARlight are designed to treat infants with abnormal head shapes from age 3 to 18 months and is available by prescription only. Since growth is the driving factor in head shape correction, the infants wear the STARband or STARlight for approximately 23 hours per day. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. The STARband and STARlight have also been cleared to treat unresolved head deformities in patients who have undergone surgery to correct craniosynostosis. The same principles of cranial remolding apply to positional deformities and post-operative patients.

VI. Predicate Devices

- STARband and Starlight, Cranial Orthosis, K140353

VII. Summary of Technological Characteristics

The CCU proposed in this 510(k) is an added software program for a previously cleared shape capture method used for the fabrication of the STARband and STARlight Cranial Orthosis. The technological characteristics and the underlying principles of operation of the STARband and STARlight Cranial Orthosis shall remain exactly the same. The inclusion of the CCU is the focus of this submission and the resulting change is indicated in **Table 1** within the feature section Reporting Software. The addition of the accuracy and capabilities study conducted on the CCU is also indicated in the Testing section.

Table 1 – Comparison of Predicate Device cleared in K140353 to the Proposed Device

Feature	From K140353	Proposed Device
Intended Use	Maintains total contact over areas of bossing or protrusion and creates voids over areas of depression or flattening to redirect cranial growth toward greater symmetry.	Maintains total contact over areas of bossing or protrusion and creates voids over areas of depression or flattening to redirect cranial growth toward greater symmetry.
Materials	Material for STARband Side Opening design and STARband Bi-Valve design - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" Pelite polyethylene foam or 1/2" Aliplast foam Material for STARlight Side Opening design and STARlight Bi-Valve design - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARlight PRO design - 1/4" – 3/8" clear Surlyn Closure for Bivalve design - Sliding/Overlap closure system - Chicago screw (or similar) for top sliding mechanism - 1" Velcro strap - 1" chafe buckle - Speedy rivets Closure for STARband Side Opening design - 1 ½" Velcro Strap - 1 ½" chafe buckle - A Gap Block made from ½" firm Pelite polyethylene foam - Large Flange, Blind Rivet Closure for STARlight Side Opening design and the STARlight PRO design:	Material for STARband Side Opening design and STARband Bi-Valve design - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" Pelite polyethylene foam or 1/2" Aliplast foam Material for STARlight Side Opening design and STARlight Bi-Valve design - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARlight PRO design - 1/4" – 3/8" clear Surlyn Closure for Bivalve design - Sliding/Overlap closure system - Chicago screw (or similar) for top sliding mechanism - 1" Velcro strap - 1" chafe buckle - Speedy rivets Closure for STARband Side Opening design - 1 ½" Velcro Strap - 1 ½" chafe buckle - A Gap Block made from ½" firm Pelite polyethylene foam - Large Flange, Blind Rivet Closure for STARlight Side Opening design and the STARlight PRO design:

Feature	From K140353	Proposed Device
	- 1" Velcro Strap - 1" chafe buckle Optional tamper resistant strap (qty 2 for the STARlight PRO design)	- 1" Velcro Strap - 1" chafe buckle Optional tamper resistant strap (qty 2 for the STARlight PRO design)
Product Design	Custom made cranial orthosis, approximately 6 to 10oz in weight. STARlight PRO weighs 12.5 to 18.5 oz.	Custom made cranial orthosis, approximately 6 to 10oz in weight. STARlight PRO weighs 12.5 to 18.5 oz.
Production	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by an approved 3-dimensional imaging device from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by an approved 3-dimensional imaging device from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine
Approved 3-Dimensional Imaging Devices	- STARscanner I - STARscanner II - Omega Scanner - scanGogh-II - 3dMDhead System - 3dMDcranial System - 3dMDflex System	- STARscanner I - STARscanner II - Omega Scanner - scanGogh-II - 3dMDhead System - 3dMDcranial System - 3dMDflex System
Reporting Software	None	- Cranial Comparison Utility (CCU)
Testing	Repeatability and Reproducibility (R&R) Analysis - Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age - Compared proposed device to cast and predicate device - Associated parameters includes A-P and M-L - Proposed device is substantially equivalent to predicate device Cranial Shape Capture Accuracy Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared proposed device to cast and predicate device - Associated Coordinate Planes (A-P; M-L; P-D and various Radius Parameters; Squareness; Flatness)	Repeatability and Reproducibility (R&R) Analysis - Utilized uniform shapes with known dimensions that represent various sizes of pediatric patients between ages 3 to 18 months of age - Compared proposed device to cast and predicate device - Associated parameters includes A-P and M-L - Proposed device is substantially equivalent to predicate device Cranial Shape Capture Accuracy Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared proposed device to cast and predicate device - Associated Coordinate Planes (A-P; M-L; P-D and various Radius Parameters; Squareness; Flatness)

Feature	From K140353	Proposed Device
	- Proposed device is substantially equivalent to predicate device Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation	- Proposed device is substantially equivalent to predicate device CCU Accuracy and Capabilities Study - Utilized a representative cranial shape that possesses a predefined shape with known dimensions - Compared CCU to manual measurements and 3D-CAD software - Accessed accuracy of measurements and capabilities of model alignment, differential maps, calculations and reporting Material Biocompatibility Testing - Cytotoxicity –Agar Diffusion - Closed Patch Sensitization - Primary Dermal Irritation

The STARband and STARlight Cranial Orthosis have previously received FDA 510(k) clearance with the STARscanner Data Acquisition System under K011350 for the STARband and under K021207 for the STARlight. The CCU does not affect the operation of the STARscanner and is not used for manufacturing of the STARband or STARlight. The CCU is a separate software program designed to present specific measurements derived from a 3D digital model of the patient's cranium. The STARband and STARlight are the same devices as previously cleared with the predicate devices. The shape capture device has the same technological characteristics. Therefore, the STARband and STARlight Cranial Orthosis are substantially equivalent to the predicate device.

The STARband and STARlight are essentially the same Cranial Orthosis. The main difference between the STARband and STARlight are the materials used to produce them. The STARband and STARlight materials have been biocompatibility tested, and the results of the tests are listed below in **Table 2**.

Table 2 – Biocompatibility Testing Summary for STARband and STARlight Cranial Orthosis

Material	Test	Results	Conclusion
Surlyn	Closed Patch Sensitization	A score of 0.00/0.00 (Test/Control) was given for both Incidence and Severity in the 24 hour and 48 hour scoring interval.	Not a Sensitizer No Erythema or Edema Formation
Surlyn	Primary Dermal Irritation	Primary Irritation Index: 0.00	Negligible Dermal Response
Surlyn	Cytotoxicity – Agar Diffusion	Cell culture treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic
Copolymer with Pelite Foam	Closed Patch Sensitization	A score of 0.00/0.00 (Test/Control) was given for both Incidence and Severity in the 24 hour and 48 hour scoring interval.	Not a Sensitizer No Erythema or Edema Formation
Copolymer with Pelite Foam	Primary Dermal Irritation	Primary Irritation Index: 0.06	Negligible Dermal Response
Copolymer with Pelite Foam	Cytotoxicity – Agar Diffusion	Cell culture treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic
Copolymer with Aliplast Foam	Closed Patch Sensitization	A score of 0.00/0.00 (Test/Control) was given for both Incidence and Severity in the 24 hour and 48 hour scoring interval.	Not a Sensitizer No Erythema or Edema Formation
Copolymer with Aliplast Foam	Primary Dermal Irritation	Primary Irritation Index: 0.00	Negligible Dermal Response
Copolymer with Aliplast Foam	Cytotoxicity – Agar Diffusion	Cell culture treated with test sample exhibited slight reactivity (Grade 1).	Non-cytotoxic

VIII. Summary and Conclusions of Non-Clinical Performance Data

The software program provides accurate information of 3D digital models from the STARscanner Data Acquisition System. The accuracy and reliability of the STARscanner has already been proven through accuracy analysis as well as repeatability and reproducibility (R&R) studies. An accuracy and capability study was conducted on the CCU and was determined to be acceptable. With sufficient accuracy, no concerns with the safety of the software program and the fact that it is not used in the manufacturing of the STARband and STARlight Cranial Orthosis, the CCU demonstrated a safety and effectiveness profile similar to the predicate device for measuring pediatric head shapes digital models provided from the STARscanner.